

Nestlé USA

800 NORTH BRAND BLVD.
GLENDALE, CA 91203

TEL (818) 549-5580
FAX (818) 549-6908



QUALITY MANAGEMENT

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

November 20, 2000

Subject: Use of the Term "Fresh" for Foods Processed With Alternative Nonthermal Technologies.

(Federal Register 41029, July 3, 2000. [Docket No. 00N-1351])

Nestlé USA, Inc. ("Nestlé") has had several products that in the past were labeled as "fresh" which were processed using new technologies, and continues to market products where a form of the term is used as a sensory modifier (e.g., "fresh tasting"). Where such a modifier can be substantiated, we strongly support the Agency's continued allowance of "fresh" in this context.

"Fresh" appropriately describes products that are manufactured / packed in a manner that delivers original strength, vigor, quality and taste

As an introduction to this topic, Nestlé would like to reference Webster's definition of "fresh" as a guide to how the term is commonly used and understood by consumers: "1. recently produced, obtained or grown; newly made; and 2. having original strength, vigor, quality, taste, etc. a) not salted, preserved, pickled." Although the Agency is specifically dealing with preservation techniques in this docket, as covered by the "not salted, preserved, pickled" part of this definition (a historical reference to when such technologies produced products that did not have original strength, vigor, quality, taste as compared to recently produced, obtained or grown products), we also think it is important to set the overall context for the discussion by reviewing "having original strength, vigor, quality, taste."

"Fresh" is a contextual (or relative) term that consumers use for items not only being recently produced, obtained or grown, but also having original quality and taste. If newer technologies deliver products that compare (or perhaps exceed) the original strength, vigor, quality, and taste of recently produced, obtained or grown products, then "fresh" would not be misleading to the consumer's expectations. The burden of proof (e.g., market research / consumer test data) would be the manufacturer's responsibility. Ultimately, consumers will decide in the marketplace the relative merit of "fresh"-labeled products. Both consumers and manufacturers already have means by which they can challenge manufacturers' claims if they believe that they are false and misleading.

00N-1351

The 1993 rule was short-term in nature and should be expanded

Nestlé believes that the original rulemaking to define the term “fresh,” which concluded in 1993, was undertaken by FDA to remedy a specific marketplace situation. The Agency’s belief at the time was that some uses of the term “fresh” on food labels and labeling were misleading, if not false. The premise of this rulemaking was to codify long-standing Agency policy that “fresh” could not be used on thermally processed or preserved foods. The structure of the rule at 21 CFR §101.95 is such that, if the term “fresh” is used in a manner that suggests the food is unprocessed, a specific exemption would be required for every preservation technique that was used for a food associated with this meaning of the term.

Seven years after this rulemaking, new food processing and preservation techniques are available, and some have application on a commercial scale. New processing technologies likely will continue to emerge and become commercially viable. Because of these developments, Nestlé believes it is appropriate to reexamine the “fresh” rule at 21 CFR §101.95, both to correct any inconsistencies and to consider accommodating new processing technologies.
quality, taste.

Response to FDA’s specific questions:

1. Do consumers associate the term “fresh” with organoleptic characteristics, nutritional characteristics, or some other characteristics?

In addition to the discussion presented under the first subhead of these comments, we believe that consumers likely have different understandings of the label term “fresh” depending on the food product that bears the term. Nestlé believes the understanding is partly based on whether the particular food is the “freshest” version of the food available in the marketplace.

For example, FDA cited in §101.95 that consumers understand pasteurized milk as “fresh” even though it is thermally processed, because it is essentially the freshest milk available. We agree with this assessment. Similarly, if all juices were pasteurized, then consumers also would understand such juices to be “fresh” because nothing fresher would be available. On the other hand, if unpasteurized fresh-squeezed juices were widely available, they would deserve to bear the term and pasteurized juices would not. Another example: Consumers might describe a pasta sauce they prepared on the stove as a “fresh” sauce even though it had been cooked; there is no fresher pasta sauce than one recently cooked. What these examples show is that thermal or other processing may be irrelevant depending on the particular food item and the way the claim is stated.

Also, to different consumers, “fresh” means that the food is recently harvested or recently prepared, or that it possesses certain nutritional attributes and organoleptic properties, such as color, aroma, and moisture conditions that are associated with recently harvested or recently prepared food. For example, if a 10-day-old refrigerated carrot had the organoleptic attributes

of a fresh-picked carrot, most consumers would probably still describe the older carrot as “fresh.” Thus, if newer packaging technologies (e.g., nitrogen-packed) essentially maintained a food in its original chemical and physical state, it would be perceived and appropriately described as “fresh” even if the item were “older” than a traditional “fresh” food would be. In other words, “fresh” is no longer necessarily a function of *time* since harvest or preparation.

2. Do consumers want a way to identify foods that taste and look fresh but have been processed to control pathogens?

Nestlé believes it would not mislead consumers to label a food that “tastes fresh” or is “freshly prepared” yet has been treated to control pathogens. An irradiated fresh fruit retains every organoleptic quality that is associated with “fresh” and would still be described as “fresh”, compared to frozen or canned fruit. The fact that it was irradiated would of course be disclosed, but it would be “irradiated fresh fruit.”

3. What does industry think the term “fresh” means?

Nestlé recognizes that the term “fresh” may have variable meanings, depending on the context of the food marketing and labeling situation. The food industry also acknowledges that the term “fresh” is a powerful and positive indicator of a product’s quality.

All food processing technologies have as their goal to treat a food in a manner that *optimizes* nutritional attributes and organoleptic properties – in short, to make a food as much “like fresh” as is possible. The realities of modern agricultural practices, food distribution and marketing, and the location of population centers distant to the agricultural centers, means that most foods have to be treated in some manner to retain nutritional characteristics and organoleptic properties over the time needed to reach the consumer. Technologies are needed to keep food “fresh,” and thus it is important to accommodate new technologies that help achieve this objective.

Nestlé believes flexibility is needed to evaluate whether the term is applicable depending on the particular food. Sanitizing processes that do not significantly alter the characteristics of a food product, such as physical, nutritional and/or organoleptic properties, should be allowed to maintain the term “fresh” on the label. And, the examples cited previously indicate that consumers use “fresh” to describe certain heat-treated foods when it happens to be the freshest version of the food available.

We also believe that “fresh” does not necessarily mean the same as “raw.” The two words may have some overlap in meaning, but they are not synonyms. “Raw” *only* connotes that the food is unprocessed, whereas “fresh” can mean several things: unprocessed, freshly baked, freshly cooked, etc. Also, a raw fruit or vegetable may no longer be fresh to a consumer if it is stale or moldy, for example.

FDA should give some consideration to new processing techniques that may be likely candidates for exemptions in 21 CFR 101.95(c) and thus be qualified to use the term "fresh." Pulsed light and ultraviolet processes usually maintain enough product characteristics to qualify for the term "fresh" while controlling pathogens and thus preserving food. Other new processing technologies, such as high pressure processing, likewise may fit this approach.

In addition, there are other technologies, not mentioned in the IFT report to FDA, that could be considered appropriate for use of the term "fresh," such as treatment of food by sanitizing gases, like ozone. We also repeat the question of whether foods treated with higher levels of ionizing radiation should not be considered "fresh," since foods treated in this manner typically do retain organoleptic properties of color, aroma and moisture characteristic of foods recently harvested. The current "fresh" rule would permit raw foods treated with up to one kilogray of irradiation to carry the term "fresh," but higher levels of irradiation might meet the necessary criteria. Nestlé believes that it would not mislead consumers to claim that irradiated food is indeed "fresh."

If a new non-thermal processing technology did not maintain the same properties in a food as in the "fresh" state, then in that particular case it would be misleading to use the term. Again, one would need to apply a case-by-case approach to evaluate whether the term were applicable or not.

4. Is the term "fresh" when applied to foods processed with the new technologies misleading to consumers?

No. See response to Question 2.

5. Do the new technologies preserve the foods?

Nestlé notes that food preservation is a matter of degree. Refrigeration alone can and does preserve food to an extent, by extending shelf life beyond that which can be achieved in ambient environment. However, foods treated through refrigeration alone most certainly are able to bear the term "fresh."

7. Are there quantifiable parameters, e.g., level of nutrients, vitamins etc., that could be measured to determine if a food is "fresh?"

Nestlé is not aware of any such parameters. With regard to nutrient levels, if one were to measure nutrients immediately after harvest, one might mistakenly define "fresh" in a manner that would exclude many foods that are sold raw. This is because nutrient profiles can degrade over the shelf life of the food. On the other hand, produce that is thermally processed immediately after harvest is likely to retain its nutrients to a much greater degree. This would lead to the ironic situation that a thermally processed food would be more "fresh" than an unprocessed food.

8. Is there a term other than "fresh" that can be used for foods processed with the new technologies?

Like the authorized term "fresh-frozen," it might be possible to develop qualifications to use with the term "fresh" that would convey both the fact of treatment and the quality associated with "fresh." For example, a term like "spectra-fresh" might convey treatment through light processes while maintaining product characteristics comparable to "fresh."

9. Would consumers understand a new term?

Nestlé believes that consumers could understand any new terminology that is explained to them.

10. What is the economic impact of allowing use of the term "fresh" for foods processed with the new technologies?

Use of the term "fresh" on any food product is completely voluntary. It is thus inappropriate to raise questions of economic impact.

11. Would allowing the term "fresh" on foods processed with new technologies place small firms not able to use these technologies at an economic disadvantage?

If use of such technologies helps to increase the safety of the food supply, small food processing firms should not be viewed as economically disadvantaged. It is the responsibility of every food processing company, no matter how small, to produce products that are safe.

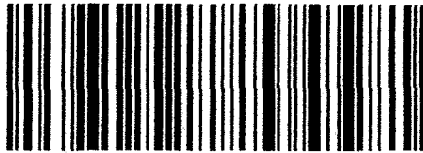
Thank you for the opportunity to comment on this important issue.

Sincerely,



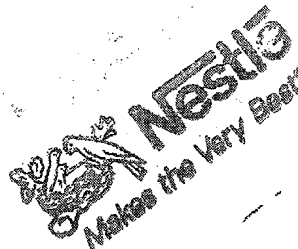
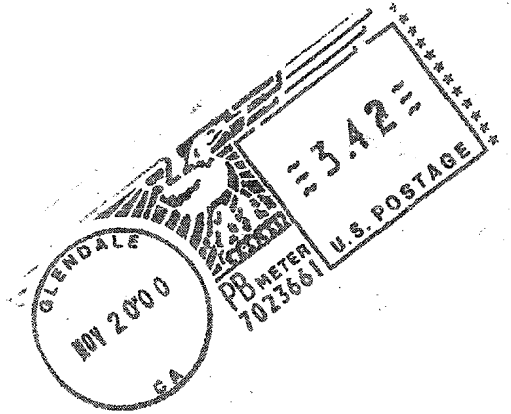
Kenneth Mercurio
Director, Labeling and Nutrition

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(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852



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